PILOT STUDY

Safety of Intravenous Infusion of BPC157 in Humans: A Pilot Study

Edwin Lee, MD, FACE; Kailynd Burgess

ABSTRACT

Background • For years, the peptide Body Protection Compound 157 (BPC-157) has been used to treat partial muscle or tendon tears. Few studies on humans have been published, with none on the intravenous use of BPC-157 in humans.

Objective • This IRB-approved study was conducted to assess whether intravenous BPC-157 is safe in humans.

Methods • Baseline blood work and vital signs were obtained from 2 participants before and after each infusion. On day 1, 10 mg of BPC-157 in 250 cc of normal saline was infused over one hour. On day 2, fasting blood work was repeated, vital signs were recorded, and 20 mg of BPC-157 in 250 cc of normal saline was infused over one hour. On day 3, fasting blood work and vital signs were repeated. Patients were questioned about any side effects at each appointment.

Setting • This study was performed at a private clinic in Florida.

Participants • Two patients participated: a 58-year-old Asian male and a 68-year-old Caucasian female, each of whom had received intravenous BPC-157 before this trial.

Results • The infusions of BPC-157 resulted in no measurable effects on the tested biomarkers of the heart, liver, kidneys, thyroid, or blood glucose levels. The BPC-157 peptide infusion was tolerated, with no side effects reported.

Conclusion • Intravenous infusion of up to 20 mg of BPC-157 in 2 healthy adults showed no adverse effects and was well-tolerated. The results of this pilot study showed the safety of BPC-157 in humans. Future studies are also needed to confirm the safety of intravenous BPC-157 in humans. (*Altern Ther Health Med.* [E-pub ahead of print.])

Edwin Lee, MD, FACE, Assistant Professor, Internal Medicine at the University of Central Florida College of Medicine, Orlando, FL, USA. **Kailynd Burgess**, College Student at the University of Florida, FL, USA.

Corresponding author: Edwin Lee, MD
E-mail: Info@DrEdwinLee.com

BACKGROUND OF BPC-157

In 1993, Dr. Predrag Sikiric of Croatia isolated the peptide Body Protective Compound (BPC-157) from human gastric juice. Both *in vitro* and *in vivo* animal studies on BPC-157 have shown it to have many restorative properties. It can help repair tendons, ligaments, muscles, nerves, bone fractures, teeth, and corneas, and promote recovery from traumatic brain injury.[1-13] BPC-157 has been shown to reduce inflammation in different animal models.[14,15]

BPC-157 has been very popular among athletes and weightlifters and is nicknamed Wolverine Peptide. It has been used to help recover joint injuries with partial muscle, cartilage, or tendon tears. People obtain it from online peptide websites for research purposes only. Products sold by online peptide stores are concerning because these unregulated substances may be unsafe.

To date, BPC-157 from a compounding pharmacy has been the subject of only two published studies investigating its use in humans. The first study examined intra-articular injection of BPC-157 for multiple types of knee pain. In this trial, 14/16 patients reported knee pain relief after 1 intra-articular BPC-157 injection. There were no reported side effects, and the treatment was well tolerated.[16] In the second study, intravesical injection of BPC-157 was administered to 12 women with moderate to severe interstitial cystitis. These women had no success after using pentosan polysulfate for over 1 year. After a single BPC157 injection of 10 mg into the area of intense inflammation, 10/12 women had 100% improvement and 2/10 had 80% improvement in their symptoms of bladder pain syndrome.[17] Furthermore, BPC-157 is reportedly safe, without adverse effects in animal trials, and lethal dose (LD1), in which 1% of subjects die, was not achieved in toxicology studies.[18-20]

The pharmacokinetics, excretion, metabolism, and distribution profiles of BPC-157 were performed in rats and beagle dogs. After intramuscular and intravenous administration of Tritium-labeled BPC-157, the elimination

half-life of BPC-157 was less than 30 minutes. For all doses used in rats and beagle dogs, BPC-157 showed linear pharmacokinetics. The major excretion pathways of BPC-157 involve the kidneys and biliary tract. BPC-157 is a 15-amino acid peptide. It is eventually metabolized into its constituent amino acids which can be reused by the body.[21]

As of September 2023, the FDA has banned many peptides owing to the lack of data showing their safety and efficacy. BPC-157 is on the list of the banned peptides.[22] As of March 2025, the FDA ban on peptides has not been finalized, awaiting the outcome of a pending lawsuit.[23] Performing a phase 1 clinical trial to establish the safety of BPC-157 in humans is estimated to cost more than one million dollars. Since BPC-157 is a peptide and not a pharmaceutical drug, it is unlikely that a large corporation will conduct a phase 1 clinical trial on it. However, we can perform a simple trial to show that intravenous use of BPC-157 is safe. Anecdotally, BPC-157 has been used intravenously in many clinics throughout the country to reduce pain and heal musculoskeletal injuries. No side effects have been reported by physicians who have prescribed it.

To this end, this study assesses the safety of intravenous compounded BPC-157 in humans before the FDA officially bans the use of BPC-157.

METHODS

We conducted a pilot study at the Institute for Hormonal Balance, in Orlando, Florida. This study was IRB-approved (IRCM-2024-402) by the Institute of Regenerative and Cellular Medicine, Santa Monica, California.

Inclusion Criteria

Any relatively healthy patient over 40 years old who agreed to test the intravenous infusion of BPC-157 was recruited into this trial. They were recruited at the Institute for Hormonal Balance, in Orlando, Florida.

Exclusion Criteria

Any patient with a chronic kidney disease, diabetes, hypothyroidism, liver failure, pregnancy, or heart condition was excluded.

Patients

The study included one Caucasian female and one Asian male participant. Their ages ranged from 58 to 68 years old. Neither patient had any acute pain or musculoskeletal injuries. Both patients covered the cost of BPC-157 and lab work totaling $1000; no honorarium was provided for this experimental therapy. Both patients signed informed consent forms and were aware that this peptide was not FDA-approved. In addition, both patients volunteered for the study to demonstrate the safety of BPC-157 so that the FDA might allow compounding pharmacies to manufacture this peptide.

Patient 1 is a 68-year-old Caucasian female with a history of thalassemia and is on Progesterone 200 mg oral and Estradiol patch 50 mcg. She takes several supplements: Magnesium, Fish Oil, Nitric Oxide, Resveratrol, and Vitamin D.

Patient 2 is a 58-year-old Asian male, without any medication, but takes Vitamin D and B Complex vitamins.

Procedure

Peptide BPC-157 was obtained from a 503A compounding pharmacy (unwilling to disclose its name for personal reasons) in the United States. This compounding pharmacy is aligned with its state board and FDA inspections. Their BPC-157 has a certificate of analysis and has been verified by independent laboratories to be free of endotoxins. The concentration of BPC-157 is 2 mg/ml with 1 vial containing 5 ml of BPC-157 for a total dose of 10 mg per vial. The lot number for BPC-157 was #1839016, with the beyond-use date (BUD) of 8/2/24.

On day 1, baseline fasting blood was drawn, and then vital signs were obtained before and after the IV infusion of BPC-157 in one arm. 10 mg of BPC-157 was mixed with 250 cc of normal saline and infused over one hour. On day 2, fasting blood work was repeated, vital signs were recorded, and another IV was inserted into each patient's other arm. 20 mg of BPC-157 was mixed with 250 cc of normal saline and infused over 1 hour. On day 3, fasting blood work and vital signs were repeated. The patients were questioned about any side effects, which were also monitored during the infusions. Blood work included Comprehensive Metabolic Panel (CMP), Complete Blood Count (CBC), Creatine Phosphokinase (CPK) with isoenzymes, B-type Natriuretic Peptide (BNP), Thyroid Stimulating Hormone (TSH), Red Blood Cell (RBC) Magnesium, and Cardio C-Reactive Protein (CRP).

Patients were questioned during and after the infusion of BPC-157 about reactions including nausea, diarrhea, vomiting, hiccups, flatulence, constipation, swelling, dry mouth, dry eyes, belly pain, fatigue, anorexia, myalgia, joint aches, headache, sweating, muscle spasm, rash, hot flashes, and shortness of breath.

Materials

Blood tests were performed for each of the patients to observe the effects of BPC-157. All the blood samples were sent to Access Medical Labs (Jupiter, FL). CMP was assessed using the Atellica Chemistry (Siemens, Germany) instrument, which employs enzymatic and colorimetric methods. CRP was evaluated using Atellica Chemistry (Siemens, Germany), which relies on turbidimetry to measure latex reagent particle coating anti-CRP antibody. TSH and BNP were determined by the Atellica IA (Siemens, Germany), which utilizes chemiluminescence detection. CBC was determined using the ADVIA 2120i (Siemens, Germany) instrument, relying on the cytochemical method. The RBC Magnesium was assessed on the 8800 ICP-MS (Agilent Technology, California) instrument, relying on inductively coupled plasma mass spectrometry. The CPK isoenzyme was analyzed on the Spife Touch (Helena Laboratories, Texas), employing enzymatic electrophoresis.

Table 1. Vital Signs and Blood Results for Patient 1 (68-Year-Old Female)

Patient 1: 68-year-old female	7/29/24 Baseline	7/30/24	7/31/24
BP- 157 dosage	10 mg in 250 cc of saline IV over 1 hour	20 mg in 250 cc of saline IV over 1 hour	
Vital signs before IV	126/79 Pulse 75	128/76 Pulse 78	No IV done
Vital signs after IV	128/78 Pulse 76	125/75 Pulse 77	127/78 Pulse 76
	Day 1	**Day 2**	**Day 3**
White blood cell	7.0	9.7	6.9
Hemoglobin	11.8	11.1	11.3
Hematocrit	42.9	38.3	42.5
Platelet	Cancelled Clumping	304	244
Glucose	88	89	92
Bun	14	15	17
Creatinine	0.6	0.9	0.6
Sodium	143	138	141
Potassium	4.1	4.6	4.7
Chloride	110	107	110
CO_2	27	25	28
Calcium	9.2	8.9	9.0
Total Protein	6.2	6.1	6.2
Albumin	3.8	3.5	3.8
Globulin	2.4	2.6	2.4
Total Bilirubin	0.5	0.6	0.7
Alkaline Phosphatase	39	43	42
ALT	16	21	7
AST	20	19	21
eGFR	106	66	106
Cardio CRP	0.3	0.4	0.4
BNP (nl < 100 pg/ml)	31	22	18
Creatine Kinase (CK)	50	65	72
CK- MM	100	100	100
CK - MB	0	0	0
CK – BB	0	0	0
RBC Magnesium	3.23	3.77	3.57
TSH	1.659	1.361	2.029

Table 2. Vital Signs and Blood Results for Patient 2 (58-Year-Old Male)

Patient 2: 58-year-old male	7/29/24 Baseline	7/30/24	7/31/24
BPC-157 dosage	10 mg in 250 cc of saline IV over 1 hour	20 mg in 250 cc of saline IV over 1 hour	
Vital Signs before IV	146/86 Pulse 54	132/81 Pulse 55	No IV done
Vital Signs after IV	143/84 Pulse 56	134/79 Pulse 54	134/80 Pulse 54
	Day 1	**Day 2**	**Day 3**
White blood cell	5.9	5.9	6.0
Hemoglobin	14.6	14.4	15.1
Hematocrit	46.3	46.7	48.6
Platelet	236	230	259
Glucose	95	82	92
Bun	13	21	17
Creatinine	0.9	0.9	0.9
Sodium	143	144	144
Potassium	4.0	5.1	4.8
Chloride	107	110	109
CO_2	28	22	28
Calcium	9.4	8.4	9.1
Total Protein	6.9	6.8	7.0
Albumin	4.2	4.5	4.2
Globulin	2.7	2.3	2.8
Total Bilirubin	0.5	0.5	0.7
Alkaline Phosphatase	90	79	79
ALT	15	22	14
AST	19	37	20
eGFR	92	92	92
Cardio CRP	1.8	1.4	1.1
BNP (nl <100 pg/ml)	14	10	10
Creatine Kinase (CK)	152	160	169
CK- MM	100	100	100
CK - MB	0	0	0
CK – BB	0	0	0
RBC Magnesium	4.99	5.13	5.46
TSH	0.808	1.257	1.213

RESULTS

From the first infusion until 24 hours after the second infusion, participants complained of no adverse reactions mentioned previously, nor did they report side effects from the intravenous infusion of BPC-157. Table 1 details the vital signs and results of lab work done for patient 1 (68-year-old female), and Table 2, for patient 2 (58-year-old male).

DISCUSSION

We wanted to investigate the safety of intravenous BPC-157 in humans. This study showed that it did not elevate the blood pressure or heart rate. A clinically insignificant minor elevation of CK occurred (Patient 1 – 50, 66, 72; and Patient 2 – 152, 160, 169) where the normal reference range for CK is 40-331 U/L. Neither patient showed evidence of any elevation in cardiac CK. In addition, both volunteers experienced a minor decline in BNP (Patient 1 – 31, 22, 18 and Patient 2 – 14, 10, 10) where normal BNP is less than 100 pg/ml. BPC-157 showed no measurable adverse effects on the cardiac biomarkers.

The study also showed that BPC-157 did not affect the kidneys. Although patient 1 had a slight increase of Creatinine on day 2 from 0.6 to 0.9, on day 3, it went back to 0.6. Her eGFR fluctuated from 106 on day 1 to 66 on day 2; on day 3, it returned to 106. She might have been dehydrated in the morning on day 2 when she had her blood sample collected. If a dose of 10 mg of BPC-157 had initiated kidney failure, her kidney function would have been worse the next day after 20 mg of BPC-157. Fortunately, her Creatinine went back to baseline at 0.6. Patient 2's Creatinine was stable at 0.9, and his eGFR was consistently over 60. If BPC-157 affected kidney function, then we would see a decline in eGRF and a rise in Creatinine for both patients. Both patients' TSH varied slightly, and from baseline to day 3, both had an increase in TSH of 0.4, which is clinically irrelevant. In addition, intravenous BPC-157 did not affect the liver, glucose levels, or RBC magnesium.

In 2024, a task force comprised of physicians, pharmacists, and attorneys conducted an unpublished survey to save peptides prior to the Pharmacy Compounding Advisory Committee's (PCAC) meetings on October 29 and December 4, 2024.[24,25] This survey inquired how many prescriptions for peptides had been dispensed by compounding pharmacies between 2018 and 2024 and whether any side effects had been reported. Within that duration, 503A compounding pharmacies fulfilled over 500 000 prescriptions for BPC-157.[24,25] Patients reported no side effects of BPC-157 to these pharmacies. Anecdotal data from physicians indicated no side effects upon administering BPC-157 injection or intravenous infusions. Over 8500 people have signed a petition to save peptides at https://savepeptides.org, a non-profit organization started by the current study's author, Edwin Lee. Many who signed the petition have benefited from peptides, including BPC-157, to recover faster from a variety of conditions, such as musculoskeletal or joint injuries. As of September 2023, the FDA has banned many peptides due to the lack of data showing their safety and efficacy. BPC-157 is on the list of the banned peptides.[22] Legally,

the FDA has no issues with physicians using peptides, but they prohibit the 503A compounding pharmacies from producing them. Evexias has filed a lawsuit against the FDA over the ban on peptides, but so far, no decision has been finalized in this case.[23] The new administration of President Trump may change the FDA's previous ban on peptides and allow them to be used. Although there are few human studies on BPC-157, the data shows it is safe, and a lethal dose (LD1) was not achieved in rodent toxicology studies.[18-19] In a toxicity study using Sprague-Dawley rats, a single dose of 20 mg/kg intramuscular BPC-157 resulted in no deaths or adverse effects. Also, a dose of 10 mg/kg in beagle dogs showed no adverse effects.[20] In our study, the maximum dose of 20 mg produced no side effects, without any clinically relevant changes in serum biomarkers, chemistry, or hormone levels.

The 2 patients in this study had received BPC-157 intravenous to help relieve a previous acute musculoskeletal injury and used a dose of 5 mg without any issues. The current study's author, Edwin Lee, has prescribed intravenous BPC-157 of 5 mg since 2018 to many patients for acute musculoskeletal injuries and observed no side effects. Some of his patients have received multiple doses of BPC-157 intravenous for a recurring injury, without ever witnessing any delayed allergic reactions to these infusions. This study, although of very short duration, showed that intravenous BPC-157 did not affect the heart, liver, kidneys, blood pressure, heart rate, glucose levels, thyroid, or RBC magnesium. For this study, we used up to 20 mg of intravenous BPC-157 with no side effects reported, and the treatment was tolerated.

The opioid epidemic poses a grave challenge to public health, affecting individuals and communities across the country. In 2020, the United States estimated 69,061 deaths related to opioid use. According to the United States Congressional Joint Economic Committee, these deaths cost the economy nearly $1.5 trillion.[26] With such a staggering number of opioid-related deaths and the high economic burden, exploring effective alternatives for pain management, particularly in post-surgical settings, is crucial.

BPC-157 offers a promising alternative to traditional opioid medications. BPC-157 promotes tissue regeneration, particularly in healing muscle, tendon, and ligament injuries. BPC-157 can promote healing through multiple pathways including the vascular endothelial growth factor (VEGF) expression in wounded skin tissues, extracellular signal-regulated kinases 1 and 2 (ERK1/2) as well as their downstream targets, including c-Fos, c-Jun, and early growth response protein 1.[3,18] In 2005, Dr. Sikiric and his associates were the first to document the use of BPC-157 to heal a full-torn Achilles tendon tear in rats in 21 days without having to perform surgery. BPC-157 improved the quantity of type 1 collagen, promoted better organization of collagen fibers, and advanced vascular appearance. In addition, BPC-157 improved the biomechanical function of the healed Achilles tendon.[5,27]

The mechanisms through which BPC-157 operates are noteworthy. By interacting with various neurotransmitter systems (specifically prostaglandins, dopamine, and serotonin), it may help alleviate pain, without the addictive potential associated with opioids. Prostaglandins are involved in the inflammatory response and pain signaling, while dopamine and serotonin play critical roles in mood regulation and the overall perception of pain.[8,28,29] By modulating these systems, BPC-157 could reduce both the sensation of pain and the psychological burden that often accompany post-surgical recovery.

The safety profile of BPC-157 is another significant advantage over the use of opioids, which can lead to dependency and numerous side effects. In this study, BPC-157 has been well tolerated with no adverse effects. Other trials are testing the safety and efficacy of BPC-157. One of the trials (IRCM-2024-391) is a single-blinded prospective study examining the efficacy of BPC-157 in the recovery of patients undergoing knee and shoulder surgery. Another trial (IRCM-2024-416) is a prospective, open-label observational study examining the safety and efficacy of BPC-157 injections in patients. Promising safety and efficacy results of BPC-157 in clinical trials would make it an appealing candidate for long-term pain management strategies, particularly in vulnerable populations who may be at higher risk for opioid addiction.

As research continues to uncover the potential applications of BPC-157, it is important to conduct rigorous clinical trials to establish comprehensive data on its efficacy and safety. Integrating alternative pain management strategies like BPC-157 into clinical practice could provide a pathway for reducing reliance on opioids and alleviating the ongoing public health crisis. In doing so, healthcare providers can promote safer, more effective means of managing pain while fostering recovery and improving the quality of life for patients.

As mentioned, people go online to obtain peptides sold for research purposes only. However, these unregulated products have safety concerns. We strongly recommend obtaining injectable peptides from 503A compounding pharmacies, which operate under the oversight of their state boards of pharmacy and adhere to the United States Pharmacopeia standards. In addition, these peptides are independently tested for endotoxins and stability. They are verified to contain the product on the label.[30] We hope that the FDA, in the future, will seriously consider reclassifying BPC-157 from Category 2 (not enough safety data) to Category 1 (allowing compounding pharmacies to produce peptides). Such a change would permit physicians to order this natural peptide from FDA-regulated compounding pharmacies for patients in need.

Limitations

Since this study was not funded, it lacked a large sample size, a sham control group, and a longer timeframe. The cost of performing more extensive research would have been

prohibitive. There was no scope for potential bias in terms of the participants since they could not alter the results of their blood work.

The study did have some strengths- it was done at a single center, all the blood work was performed at one laboratory, and the 2 volunteers were healthy.

CONCLUSION

Short-term intravenous infusion of up to 20 mg of BPC-157 in 2 healthy adults showed no measurable adverse effects on cardiac biomarkers, with no elevation in CPK, BNP, Cardio-CRP, blood pressure, or heart rate. No effect on the liver, blood glucose levels, thyroid, or RBC Magnesium was observed. No side effects were reported, and the infusion was well-tolerated. Further studies are needed to confirm the safety of intravenous BPC-157 in humans.

AUTHOR DISCLOSURE STATEMENT

The authors declare no conflict of interest in the authorship or publication of this manuscript.

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